

MedStar Health, Inc. POLICY AND PROCEDURE MANUAL

POLICY NUMBER: MP.083.MH
REVISION DATE: 04/15
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SUBJECT: Proton Beam Therapy (PBT)
INDEX TITLE: Medical Management
ORIGINAL DATE: January 2013

This policy applies to the following MedStar Health lines of business:
(Check those that apply.)

COMMERCIAL	<input type="checkbox"/> HMO	<input type="checkbox"/> PPO	<input type="checkbox"/> Fully Insured	<input type="checkbox"/> Individual Product	<input type="checkbox"/> Marketplace (Exchange)	<input checked="" type="checkbox"/> All
GOVERNMENT PROGRAMS	<input type="checkbox"/> MA HMO <input type="checkbox"/> MA PPO <input type="checkbox"/> MA C-SNP <input type="checkbox"/> MA D-SNP <input checked="" type="checkbox"/> MA All					
	<input type="checkbox"/> Medicaid					
OTHER	<input checked="" type="checkbox"/> Self-funded/ASO					

I. POLICY

It is the policy of MedStar Health, Inc. to cover Proton Beam Therapy (PBT when it is medically necessary (Refer to CRM.015.MH Medical Necessity policy) and covered under the member's specific benefit plan.

All denials are based on medical necessity and appropriateness as determined by a MedStar Health, Inc. Medical Director (Medical Director).

II. DEFINITIONS

Bragg Peak is an intensity radiation dose peak resulting from a proton passing through living tissue.

Cyclotron (or synchrotron) is a circular particle accelerator (nuclear reactor) that smashes atoms and propels charged particles (e.g. protons) through an alternating electrical field in a constant magnetic field.

Dose-Volume Histogram (DVH) is a concept used in radiation planning. The purpose of a DVH is to summarize 3D dose distributions in a graphical 2D format. DVHs can be visualized in either of two ways: differential DVHs or cumulative

DVHs.

Proton Beam Therapy

Other generic names:

- Charged particle radiotherapy
- Compact proton therapy
- Intensity modulated proton therapy (IMPT)
- Medical charged-particle radiation therapy system
- Particle beam radiotherapy
- Particle beam therapy
- Particle irradiation
- Pencil-beam scanning
- Proton beam therapy;
- Proton beam therapy system
- Proton cancer therapy radiotherapy systems
- Proton irradiation
- Proton radiotherapy
- Proton therapy
- Proton treatment
- Spot-scanning

(Refer to Medical Description section)

III. PURPOSE

The purpose of this policy is to define the appropriate indications for Proton Beam Therapy.

IV. SCOPE

This policy applies to various MedStar Health, Inc. Departments as indicated by the Benefit and Reimbursement Committee. These include but are not limited to Medical Management, Benefit Configuration and Claims Departments.

V. PROCEDURE

A. Medical Description / Background

Proton beams are produced by a cyclotron or synchrotron, a circular particle accelerator (nuclear reactor) that propels charged particles (e.g., protons) by an alternating electrical field in a constant magnetic field.

Proton beam therapy, a form of stereotactic radiosurgery, delivers a uniform and high dose of radiation to the targeted tumor. However, unlike x-rays, proton particles deposit their radiation energy as they slow down, culminating in an intensity dose peak, also called the Bragg Peak. The depth of the peak can be controlled by the amount of the proton's energy. While the unaltered Bragg Peak is measured in millimeters, it can be spread out to encompass whole or partial volumes of a tumor. Like other conformal radiation modalities, proton beams can be precisely delivered to the tumor volume without harming surrounding healthy tissue or critical organs. Proton beams theoretically enable patients to tolerate a higher total radiation dose than can be achieved with photon radiation for many tumor sites without concomitantly increasing radiation side effects.

Some examples of the company systems used are:

- STAR® (Stereotactic Alignment for Radiosurgery)
- Conforma 3000®
- PROBEAT®

Prostate Cancer- There is as yet no good comparative data to determine whether or not Proton Beam Therapy for prostate cancer is superior, inferior, or equivalent to external beam radiation or brachytherapy in terms of safety or efficacy.

B. Specific Indications

Proton beam therapy may be indicated for any of the following conditions:

1. Central nervous system tumors - benign or malignant (including but not limited to primary and variant forms of astrocytoma, glioblastoma, medulloblastoma, acoustic neuroma, craniopharyngioma, benign and atypical meningiomas, pineal gland tumors, and arteriovenous malformations)
2. Head and neck lesions- malignant
3. Intraocular melanomas
4. Pituitary neoplasms
5. Lung cancers, especially non-small cell lung cancer (NSCLC)
6. Retroperitoneal and extremity sarcoma- unresectable
7. Skull base or axial skeleton conditions - benign or malignant (including but not limited to chordomas and chondrosarcomas)
8. Solid tumors in children up to age 18
9. Member is enrolled in an appropriate clinical trial/registry for planned assessment and publication. (Refer to Clinical Trials policy).



And

When all of the following are met:

1. The dose volume histogram (DVH) illustrates at least three (3) critical structures or organs protected by the use of proton beam therapy
And
2. The dose to control or treat the tumor cannot be delivered without exceeding the tolerance of the normal tissue
And
3. Documentation indicates that doses generally thought to be above the level otherwise attainable with other radiation methods might improve control rates
Or
Documentation indicates that higher levels of precision associated with proton beam therapy compared to other radiation treatments are clinically necessary.

C. Limitations

Proton beam therapy is not indicated for cancers that are widely disseminated, have hematogenous metastases, or as a short term palliative procedure.

D. Information Required for Review

In order to assess medical necessity adequate information must be provided by the treating physician. Necessary information includes, but is not limited to, the following:

1. Member's age and diagnosis
2. History and physical
3. Date of service
4. Reason for service
5. The planned course of therapy, type and delivery of treatment, level of clinical management involved and ongoing documentation of any changes in the course of treatment
6. The dose volume histogram (DVH) indicates at least three (3) critical structures or organs protected by the use of proton beam therapy
7. Documentation that the dose to control or treat the tumor cannot be delivered without exceeding the tolerance of the normal tissue
8. Documentation indicates clinical rationale that doses generally thought to be above the level otherwise attainable with other radiation methods might improve control rates



OR

Documentation indicates that higher levels of precision associated with proton beam therapy compared to other radiation treatments are clinically necessary.

9. The name of the physician or non-physician practitioner responsible for and providing the care of the member

E. Review Process

1. The Medical Management Ancillary Service staff reviews the request. If the case does not meet the established criteria, it is referred to a MedStar Health, Inc. Medical Director (Medical Director).
2. If referred, the Medical Director determines if the requested service is medically necessary and appropriate.
3. The Medical Management Ancillary Service staff completes the review process and communicates the review decision according to the Timeliness of UM Decisions policy for the member's benefit plan.

F. Variations

N/A

G. Records Retention

Records Retention for documents, regardless of medium, are provided within the MedStar Health, Inc., and as indicated in the MedStar Health, Inc. Division Policy and Procedure CORP.028.MH Records Retention.

Unless otherwise mandated by Federal or State law, or unless required to be maintained for litigation purposes, any communications recorded pursuant to this Policy are maintained for a minimum of ten (10) years from the date of recording.

H. Codes

The following codes for treatments and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Applicable CPT codes:

77520	Proton treatment delivery; simple, without compensation
77522	Proton treatment delivery; simple, with compensation
77523	Proton treatment delivery; intermediate
77525	Proton treatment delivery; complex

I. References

Medical Literature/Clinical Information

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Regulatory/Government Source

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